

Certificate of Analysis

Name of Product	Favipiravir		
Batch No.	20200605	Mnf. Date	2020/06/13
Test Date	2020/06/13	Report date	2020/06/14
Retest date	2022/06/12	CAS No.	259793-96-9
Quantity	72kg	Standard	Enterprise standard

Item	Specification	Results
Appearance	White to light yellow powder.	Conform
Solubility	Soluble or sparingly soluble in acetonitrile, sparingly soluble in methanol, slightly soluble in water.	Conforms
Identification	1) The retention time of major peak in the chromatogram of sample solution should correspond to that of the standard solution as obtained in chromatographic assay by HPLC.	Conform
	2) IR spectrum conforms to the standard.	Conform
Water (by KF)	≤ 0.5%	0.14%
Residue on ignition	≤ 0.1%	0.07%
Heavy metals	≤ 20ppm	Conform
Chloride	≤ 0.06%	Conform
Melting point	188 ~ 193℃	Conform
Related substances	Any Single Impurity ≤ 0.05%	0.01%
	Total Impurities ≤ 0.5%	0.03%
Residue solvents	Dichloromethane ≤ 600ppm	ND
	Toluene ≤ 890ppm	ND
	N,N-Dimethylformamide ≤ 880ppm	ND
	Acetonitrile ≤ 410ppm	50ppm
	Methanol ≤ 3000ppm	47ppm
	Toluene ≤ 890ppm	8ppm
	Ethyl acetate ≤ 5000ppm	ND
Ethanol ≤ 5000ppm	ND	

	Acetone ≤ 5000ppm	ND
	Acetic acid ≤ 5000ppm	ND
	N-heptane ≤ 5000ppm	ND
	Pyridine ≤ 200ppm	ND
	Trimethylamine ≤ 320ppm	ND
	Dicyclohexyl Amine ≤ 20ppm	ND
	Benzene ≤ 2ppm	ND
Assay (on dry basis)	98.0% ~ 102.0%	99.96%
XRD	Form A	Conforms
Particle size	D90 < 50um	21.48um
Microbial test	Total Amount of aerobe ≤ 1000 cfu/g Yeast & molds ≤ 100 cfu/g E.Coli: not detected	Conform Conform Conform
Conclusion	The test results conform to Enterprise Standard.	

Tested by: Meng Xiao

Checked by: Shen Junli

Approved by: He Youguang

